IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9351

Bartle, J. September 23, 2014

Gloria Erculiani ("Ms. Erculiani" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2005, claimant submitted a completed Green Form to the Trust signed by her attesting physician Ted M. Parris, M.D., F.A.C.C. Based on an echocardiogram dated April 2, 2002, Dr. Parris attested in Part II of Ms. Erculiani's Green Form that she suffered from moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%.[3]

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2. (...continued)
Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Dr. Parris also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

Based on such findings, claimant would be entitled to Matrix A-1,[4] Level II benefits.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, Mario J. Poon, M.D., stated that claimant had "2-3+ mitral regurgitation." Dr. Poon, however, did not provide a percentage as to the amount of claimant's mitral regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In March, 2006, the Trust forwarded the claim for review by Daniel E. Krauss, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Krauss concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her

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4. In her Green Form, claimant requested Matrix Benefits on Level A-1. Upon review of claimant's Green Form and supporting materials, the Trust determined that claimant only alleged conditions consistent with a claim for Matrix Benefits on Level B-1. The Trust does not state, however, how it reached this conclusion. Given our disposition, we need not resolve this issue.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

echocardiogram demonstrated only physiologic mitral regurgitation.[6] In support of this conclusion, Dr. Krauss stated:

> The claimant reports moderate [mitral regurgitation], which is not supported by the data. The duration of flow of the "[mitral regurgitant]" jet is only 2 or 3 frames at 30 fps, normal "backflow" associated with valve closure rather than real [mitral regurgitation]. Additionally, there is no use of [mitral regurgitation] or [left atrial] measurements used to determine the extent of [mitral regurgitation] according to the method of Singh.

Based on the attesting physician's finding that claimant had only physiologic mitral regurgitation, the Trust issued a post-audit determination denying Ms. Erculiani's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[7] In contest, claimant submitted a letter from the attesting physician, Dr. Parris, in which he stated that he re-reviewed claimant's echocardiogram and again concluded that Ms. Erculiani

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6. Physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA." See Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue at 2.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Erculiani's claim.

suffered from moderate mitral regurgitation. Dr. Parris also stated:

> 2. I see what the auditor refers to as "backflow" on some beats, but velocity is high during isovolumetric systole on other beats which is indicative of mitral regurgitation.
>
> 3. To say that there is "no" mitral regurgitation, I believe is inaccurate. While there is backflow, there are also true regurgitation jets.

Claimant contended therefore that there was a reasonable medical basis for finding moderate mitral regurgitation and that the auditing cardiologist "simply disagree[d] with Drs. Parris and Poon."

The Trust then issued a final post-audit determination, again denying Ms. Erculiani's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Erculiani's claim should be paid. On April 12, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7112 (Apr. 12, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 16, 2007. Under

the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[8] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D. F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F. 2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

In support of her claim, Ms. Erculiani asserts that there is a reasonable medical basis for her claim because the attesting physician based his finding of moderate mitral regurgitation on "a true jet of mitral regurgitation which, when measured, meets the requirements" of the Settlement Agreement. Claimant also asserts that the auditing cardiologist merely disagreed with the attesting physician and improperly substituted his own opinion. Finally, claimant argues that the attesting physician's finding was "based on sound methodology" consistent with this court's decision in Pretrial Order No. 2640 (Nov. 14, 2002).

In response, the Trust argues that Ms. Erculiani has not established a reasonable medical basis for the attesting physician's representation that claimant had moderate mitral regurgitation. Specifically, the Trust argues that the opinion of Dr. Parris lacks a reasonable medical basis because he improperly characterized backflow as mitral regurgitation and never identified a holosystolic mitral regurgitant jet with an RJA/LAA ratio of at least 20% in consecutive frames. The Trust also asserts that the auditing cardiologist properly applied the reasonable medical basis standard and neither merely disagreed with, nor substituted his opinion for that of, the attesting physician.[9]

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9. The Trust also contends that the letter of Dr. Parris should be excluded because it is not verified. We disagree. While the Audit Rules allow for the submission of verified expert opinions, (continued...)

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Erculiani suffered from moderate mitral regurgitation. Specifically, Dr. Burke observed, in relevant part:

> Upon my review of the tape, I found the echocardiogram to be a technically difficult study. My overall assessment of the mitral regurgitation was mild. This assessment includes all views, including those not used for calculation of RJA/LAA (regurgitant jet area/left atrial area) ratio. There was no recorded apical two chamber view with color flow Doppler to assess an RJA/LAA ratio.
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> ....
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> In the apical four chamber view, I also found the mitral regurgitation to be mild. Using representative beats, I calculated the RJA/LAA ratios to range from 6% to 17%. These calculations all are in the range of mild mitral regurgitation.
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> In the apical three chamber view, I also found the mitral regurgitation to be mild. I calculated an RJA/LAA ratio of 5% on a few beats with mitral regurgitation. It should be noted that, in this view ... many of the beats showed no mitral regurgitation.
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> I agree with the assessment of the Auditing Cardiologist that the duration of the flow is quite brief. This is more compatible with mild regurgitation.
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> Although I agree with the assessment of the Claimant's Attesting Physician that the jet recorded indicates mitral regurgitation and not purely backflow on all beats, I disagree with his assessment that the mitral

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9. (...continued)
it does not preclude the submission of expert opinions that are not verified. See Audit Rule 18(b).

> regurgitation is moderate and I disagree with his assessment that the velocity is high during isovolumetric systole.
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> In conclusion, there is not a reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a., which states that Claimant suffers from moderate mitral regurgitation. This conclusion is based both on my overall assessment of the tape as well as my calculation of RJA/LAA ratios in multiple views.

In response to the Technical Advisor Report, claimant argues that "[w]hile Dr. Burke's calculations may be accurate, they do not negate the reasonability of a finding of moderate mitral regurgitation in this claim." According to claimant, "a marginal difference, such as 3% in the RJA/LAA, must be expected and considered a reasonable interpretation by others."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we disagree with claimant that the determination of Dr. Poon and the letter from Dr. Parris provide a reasonable medical basis for finding that Ms. Erculiani had moderate mitral regurgitation. First, as noted previously, Dr. Poon did not provide a percentage as to the amount of claimant's mitral regurgitation. Second, Dr. Parris did not dispute the auditing cardiologist's finding that Ms. Erculiani's echocardiogram included backflow; instead, he said that it was inaccurate to say that there was "no" backflow, because the "velocity is high during isovolumetric systole on other beats which is indicative of mitral

regurgitation."[10] Notably, other than his statement that "there is mitral regurgitation in the moderate range on this study," Dr. Parris does not offer any support for his conclusion.

Dr. Burke, however, reviewed Ms. Erculiani's echocardiogram and concluded that it demonstrated only mild mitral regurgitation. In particular, Dr. Burke reviewed claimant's entire echocardiogram and determined that all of the representative cycles he reviewed demonstrated an RJA/LAA ratio of 17% or less, including many beats that "showed no mitral regurgitation." In addition, Dr. Burke "disagree[d] with [the attesting physician's] assessment that the velocity is high during isovolumetric systole." We find that neither the determination of Dr. Poon nor the letter from Dr. Parris provides a reasonable medical basis for finding Ms. Erculiani's echocardiogram demonstrates moderate mitral regurgitation.

In addition, we reject claimant's argument that the presence of moderate mitral regurgitation at any point in the study dictates that it is present throughout the study. We previously have held that "[f]or a reasonable medical basis to exist, a claimant must establish that the findings of the requisite level of mitral regurgitation are representative of the level of regurgitation throughout the echocardiogram." Mem. in

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10. We previously have noted that it is inappropriate to characterize backflow as mitral regurgitation. Mem. in Supp. of PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis of moderate mitral regurgitation.

Supp. of PTO No. 6997 at 11; see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., 543 F.3d 179, 187 (3d Cir. 2008). "To conclude otherwise would allow claimants who do not have moderate or greater mitral regurgitation to receive Matrix Benefits, which would be contrary to the intent of the Settlement Agreement." Mem. in Supp. of PTO No. 6997 at 11. Claimant makes no argument that regurgitant jet identified by her attesting physician was representative of a level of moderate mitral regurgitation throughout claimant's echocardiogram.

Finally, claimant's reliance on inter-reader variability to establish a reasonable medical basis is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. Here, the opinion of claimant's cardiologist cannot be medically reasonable where the auditing cardiologist and Technical Advisor concluded that claimant's mitral regurgitation was mild with a maximum RJA/LAA ratio of 17%. Adopting Ms. Erculiani's argument would allow a claimant to recover Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless the standards established in the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral

regurgitation. Therefore, we will affirm the Trust's denial of Ms. Erculiani's claim for Matrix Benefits.